

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/039747

International filing date: 26 November 2004 (26.11.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/617,559
Filing date: 09 October 2004 (09.10.2004)

Date of receipt at the International Bureau: 17 January 2005 (17.01.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

January 06, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: 60/617,559

FILING DATE: *October 09, 2004*

RELATED PCT APPLICATION NUMBER: *PCT/US04/39747*



Certified By

Jon W Dudas

Under Secretary
of Commerce for Intellectual Property
and Acting Director of the
United States Patent and Trademark Office

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EV511476528US

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Wenli	Cai	Middle Island, New York
Frank C.	Dachille	Amityville, New York

Additional inventors are being named on the 2nd separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max):

SYSTEM AND METHOD FOR VIRTUAL EXAMINATION

Direct all correspondence to:

CORRESPONDENCE ADDRESS

☒ The address corresponding to Customer Number:

22150

OR

☐ Firm or
Individual Name Frank Chau

Address CHAU & ASSOCIATES
130 Woodbury Road

City Woodbury

State NY

Zip 11797

Country U.S.

Telephone 516-692-8888

Fax 516-692-8889

ENCLOSED APPLICATION PARTS (check all that apply)

☒ Specification Number of Pages 27

☐ CD(s), Number of CDs _____

☐ Drawing(s) Number of Sheets _____

☒ Other (specify) PTO/SB/17

☐ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees.

FILING FEE
Amount (\$)

\$80.00

☒ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: _____
A duplicative copy of this form is enclosed for fee processing.

☒ The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government. No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

SIGNATURE

Date October 8, 2004

TYPED or PRINTED NAME Frank V. DeRosa

REGISTRATION NO. 43,584

TELEPHONE 516-692-8888

(if appropriate)

Docket Number: 8095-10

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PROVISIONAL APPLICATION COVER SHEET
Additional Page

PTO/SB/16 (09-04)

Approved for use through 07/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

First Named Inventor	Wenli Cai	Docket Number 8095-10
INVENTOR(S)/APPLICANT(S)		
Given Name (first and middle [if any])	Family or Surname	Residence (City and either State or Foreign Country)
Dongqing	Chen	Setauket, New York
Michael	Meissner	Port Jefferson, New York
George	Economos	Bayport, New York
Jeffrey	Meade	Bay Shore, New York

Number 2 of 2

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL
for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT**

(\$ 80.00)

Complete if Known

Application Number

Filing Date

First Named Inventor

Wenli Cai

Examiner Name

Art Unit

Attorney Docket No.

8095-10

METHOD OF PAYMENT (check all that apply)☐ Check ☒ Credit card ☐ Money Order ☐ Other ☐ None☐ Deposit Account:Deposit
Account
Number
Deposit
Account
Name

F. CHAU & ASSOCIATES, LLC

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Credit any overpayments☐ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 790	2001 395	Utility filing fee	
1002 350	2002 175	Design filing fee	
1003 550	2003 275	Plant filing fee	
1004 790	2004 395	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	80.00

SUBTOTAL (1) (\$ 80.00)**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

Total Claims	Extra Claims	Fee from below	Fee Paid
-20** =		18	0.00
Independent Claims	-3** =	88	0.00
Multiple Dependent		300	

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 88	2201 44	Independent claims in excess of 3
1203 300	2203 150	Multiple dependent claim, if not paid
1204 88	2204 44	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ 0.00)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for <i>ex parte</i> reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 430	2252 215	Extension for reply within second month	
1253 980	2253 490	Extension for reply within third month	
1254 1,530	2254 765	Extension for reply within fourth month	
1255 2,080	2255 1,040	Extension for reply within fifth month	
1401 340	2401 170	Notice of Appeal	
1402 340	2402 170	Filing a brief in support of an appeal	
1403 300	2403 150	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,370	2501 685	Utility issue fee (or reissue)	
1502 490	2502 245	Design issue fee	
1503 660	2503 330	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 790	2809 395	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 790	2810 395	For each additional invention to be examined (37 CFR 1.129(b))	
1801 790	2801 395	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 0.00)**SUBMITTED BY**

(Complete if applicable)

Name (Print/Type)

Frank V. DeRosa

Registration No.

43,584

Telephone 516-692-8888

Signature

Date

October 8, 2004

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Attorney Docket No.: 8095-10

U.S. Provisional Patent Application:

Title: SYSTEM AND METHOD FOR VIRTUAL EXAMINATION

Inventors: Wenli Cai
Frank Dachille
Dongqing Chen
Michael Meissner
George Economos
Jeffrey Meade

Assignee: Viatronix Incorporated

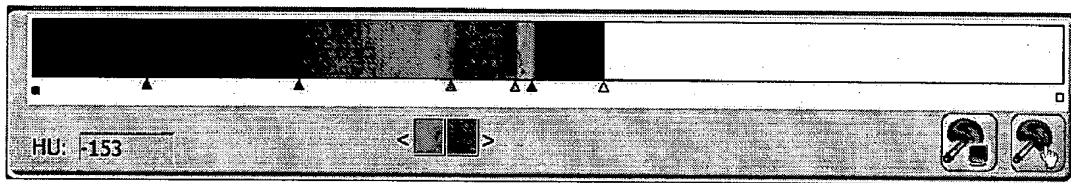
Date Deposited: October 8, 2004

F. Chau & Associates, LLC
130 Woodbury Road
Woodbury, New York 11797
Tel: (516) 692-8888
Fax: (516) 692-8889

BEST AVAILABLE COPY

Virtual Biopsy (Translucency) View Adjustments

In order to facilitate differing modalities (e.g. CT, MR) and the needs of different doctors using the MPR and endoluminal views in conjunction with the virtual biopsy mode, as well as to allow for adjustments based on changes in findings of diagnosing colon cancers, an interface for adjusting the colors and thresholds for the virtual biopsy view is needed. With the interface, a user can adjust the imaging values (e.g. Hounsfield units, raw intensity values) to which a particular color is applied in the virtual biopsy view; these values are known as thresholds. Users can also adjust the actually colors applied to different imaging values. The interface, where the user adjusts thresholds by moving sliders, and uses a color-picking dialog to select colors (colors of adjacent thresholds are linearly interpolated across a range of imaging values), is shown in the accompanying figure below.



Collaborative Virtual Examinations

The following presents a framework for the collaborative viewing of 2D/3D medical data. The old way to perform collaborative viewing of a dataset (see Kaufman patent) was to send the data to all the participants and then compute locally the views of the exam. The new proposed way is to a server-based approach in which the dataset remains at one location and the views of the examination are sent to the participants in real time.

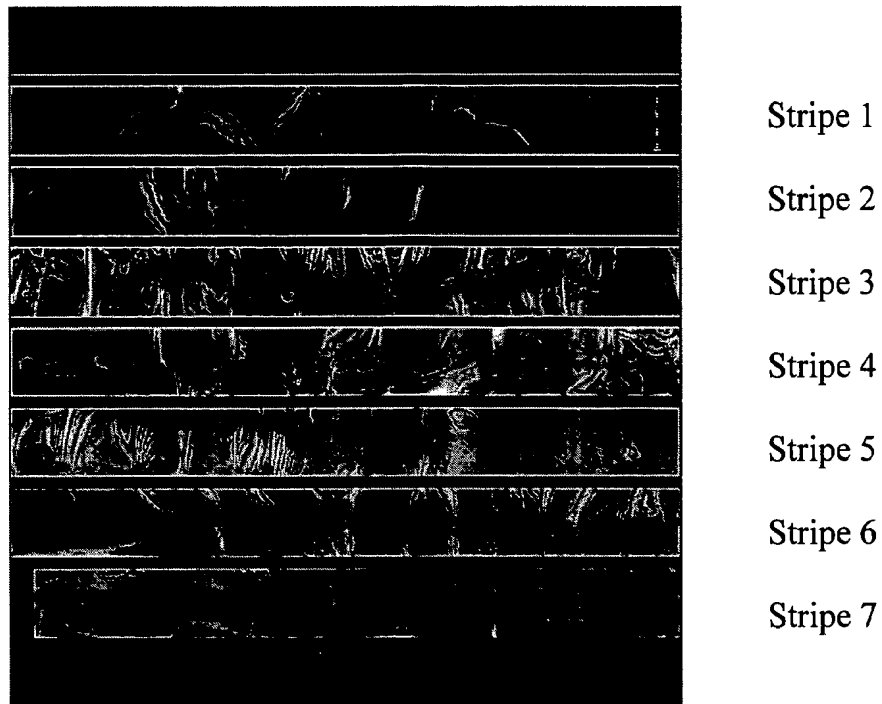
To begin a session, the principal participant initiates a session on the server. The server loads the required data and creates a stream of visual information to which the principal participant immediately connects. At this point, the other participants may connect to the stream and observe the visual exam data. Only one participant may control the content of the stream at a time. If a passive participant wishes to take control, he requests ownership from the primary participant who then may grant control. In this way, only one participant is in control at a time.

The stream may be composed of multiple sub-streams. For instance, there may be three different views of the exam subject from different directions. Some or all of these views may be updated or changed. The sub-streams are re-composed on the individual participants' computers.

A further advantage of this invention is that image generation can take place on a high-powered server and that the participants are not required to have expensive computers, but only a commodity network connection to the server.

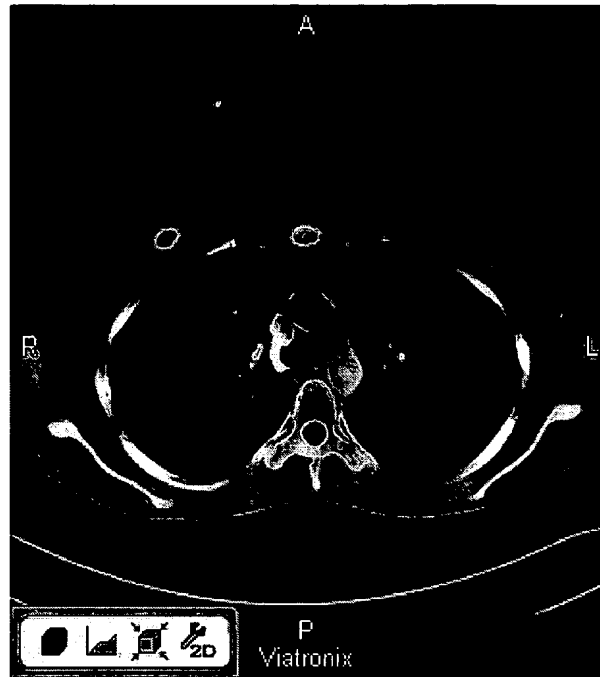
Some additional ideas for Colon and Fusion

1. Fuse and overlay secondary information on top of the file view or an overview or an endoluminal view or a curved MPR view or a double-oblique MPR view or any other non-standard 2D or 3D projection.
 - a. The fusion process is an alignment procedure that matches up features in the two data sets.
 - b. The overlay of information is a selective blending of the secondary information over top of the original information either by a simple weighted average of the two color images or by a selective (data sensitive) combination of the images (e.g., the overlaid image is a color+opacity image).
 - c. The secondary information can be data from another modality such as PET, SPECT, MRI or CT scan. It can also be information derived (computed from) either the primary modality data set or from a secondary data set. No alignment is necessary if the secondary information is simply computed or derived from the original data.
 - d. The advantage of the overlay of secondary information is that confirmation of suspicious findings is automatic because the information is available directly at the position of suspicion. Furthermore, if suspicious regions are offered by the secondary information (as in PET or CAD), then the viewer is drawn to the suspicious regions by their heightened visibility.
2. A method as defined in Claim 1, wherein the organ is a colon and the view is a file view of the colon. The secondary information overlaid could be PET information (see below).
 - a. A colon file view looks like:



It is a projection of the colon that stretches out the colon based on the centerline. This view is created using a cylindrical projection about the centerline. This means that parts of the colon that were once curved are now straightened out so this view introduces significant distortion at areas of high curvature. However, the advantage of this view is that you immediately get to see a large amount of the colon surface in a single image. Some polyps may be behind folds or stretched out to look like folds, while some folds may be squeezed to look like polyps.

In order to help differentiate polyps, stool, and folds, it would be extremely helpful to overlay information from a secondary modality. For instance, Positron Emission Tomography (PET) scanners register the amount of chemical uptake of radioactive tracers that are injected into the patient. These move to the sites of increased metabolic activity and thus show up extremely concentrated at cancer sites. Although the information from PET is not yet very detailed (it has a relatively low spatial resolution compared to CT), it is extremely helpful when overlaid or embedded over CT or other data. In this sample, the breast tumor is

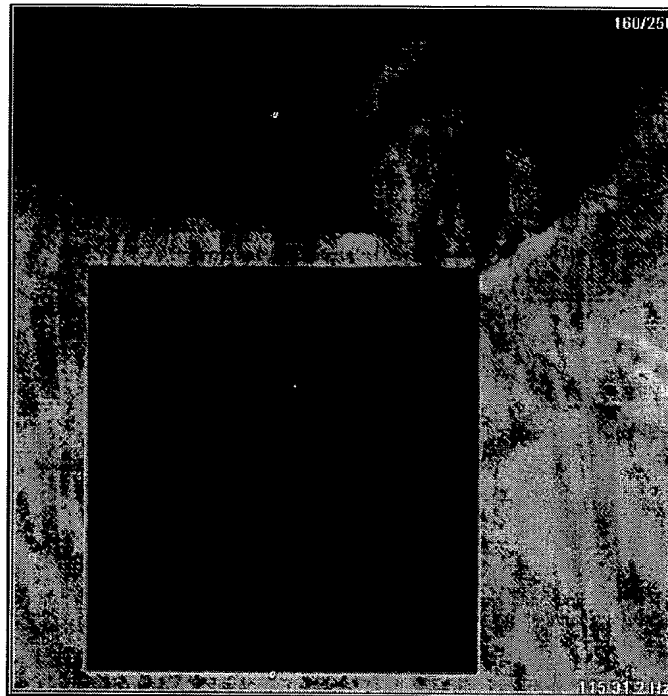


Similarly, the highlighted PET data could be overlaid on top of the filet view to indicated probable cancers. This overlay can be blended in and out with variable transparency. Data from modalities other than PET, such as SPECT or MRI, can also be overlaid and variable blended with the data, or laid out next to the CT data in alternating rows, for example.

3. In order to help differentiate polyps versus diverticula in the filet view or other 2D/3D projection view, pseudocolor the depressed and elevated regions (innie vs. outtie) differently.
 - a. The same technique of overlaying and juxtapositioning secondary information from another modality can be used to provide additional information or clues from derived or tertiary information. For instance, shape information such as curvature derived about the colon surface can be used help pseudocolor the surface. It is particularly difficult to tell the difference between a depressed diverticula and an elevated polyp in a static image such as the filet view. To help differentiate them, the shape can be computed and it can be determined at each such region to either color or highlight elevated regions and to color or de-enhance depressed regions. Another example is the overlaying of potential polyp locations over the filet view. A Computer Aided Diagnosis can be run on the colon surface and the results projected onto the filet image or any 2D or 3D image.
4. The translucent display that colon has can be expanded to use the values of a second modality (e.g., PET) instead of just the CT data. This is helpful because

the PET data can be mis-registered by several mm and be hidden under the normal surface.

- a. In the colon system, there is a view called the translucent display which shows volume rendered CT data underneath the normal colon surface. It usually shows the translucent display in just a small portion of the normal image to help give context about what is seen:



The translucent display is generated by applying a brightly colored colormap with a low, constant opacity to the CT data and volume rendering from the same viewpoint and direction as the normal image. This same technique can be used to overlay PET, SPECT, CAD, shape, other modality data, or derived data onto the normal image. So, instead of seeing the CT data underneath the color surface, you would see the other data rendered below the surface, giving you a magic window to peer into the second modality through the first modality.

3D Navigational Flight along a Pre-Computed Path with Force Feedback

It's all too easy while flying through tortuous anatomy to lose sense of direction and lose one's orientation.

The following suggests a method to enhance the user's ability to manipulate a camera in 3D space while staying true to a pre-computed optimal path using force feedback devices which can apply forces in at least two directions.

Consider any 2-axis input device; assigning the pitch of the camera to the y-axis and the heading to x-axis it is possible to apply a force in both x and y such that any errant path can be corrected. The magnitude of the force is greater the further away the camera is from the pre-computed path. When the camera is close to the path a gentle force will be applied to "guide" the user along.

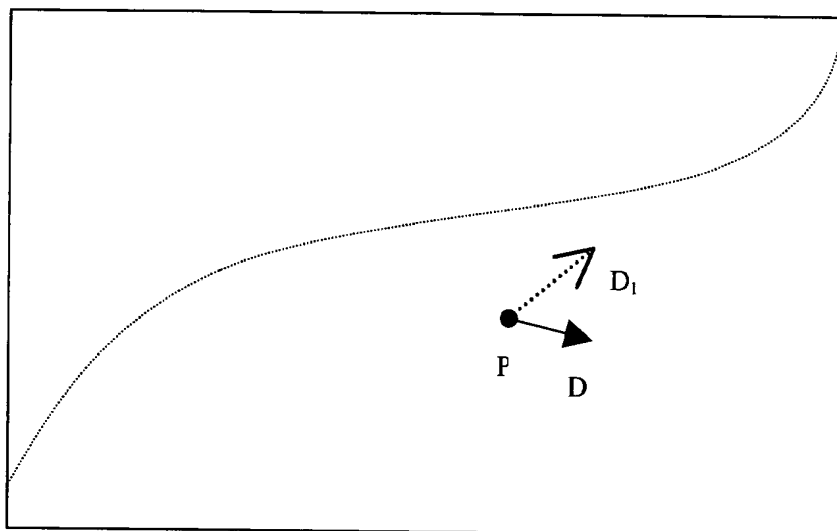


Figure 1

In the above figure, if we have a camera with position P and direction D ; we can compute the corrective force that must be applied to the input device to yield the direction D_1 .

Perceived Endoluminal Flight Speed

A doctor performing diagnostic examinations of colon lumen using 3D endoluminal flight must be able to effectively and accurately process the information that is presented during flight. In addition to other factors, the speed of flight determines how much and how well information is being presented, and as such can affect how quickly a doctor can process views accurately. Though traveling at a constant speed, as measured in millimeters/second, the speed of flight *as perceived* by the user is dependant on the distance from the viewpoint to the nearest point on the colon lumen surface. At a constant speed, the less insufflation that an area of the colon received, the more difficult it becomes for the user to focus on a particular area on the lumen wall, because of the perception of increased flight speed. As a user is flying thru the colon lumen, the perceived changes in flight speed through areas of varying insufflation can be very distracting to the user. Thus, it is necessary to bring the perception of flight speed during flight to as close to a constant as possible.

The method used to modulate the *actual* flight speed in order to maintain a constant *perceived* flight speed, if the user requests such modulation, was to first determine an upper and lower threshold of insufflation widths (the straight-line distance from the lumen surface point closest to the field of view to the closest point on the opposite lumen wall) at which to modulate the actual flight speed. While flying through areas of insufflation width greater than the upper threshold, the amount of change in the perceived speed was minute enough such that it was not distracting to the user, and as such did not need modulation. For widths less than the lower threshold, the actual speed is modulated using the lower threshold width. A neighborhood sample of insufflation widths are taken and averaged, so that sharp changes in insufflation width would not result in undesirable large changes in flight speed. Finally, the resulting change in velocity is calculated as a percentage of the averaged radius to the upper threshold radius.

The result is a gradual reduction of *actual* flight speed as the user's field of view encounters and passes thru areas of low insufflation, resulting in little to no *perceivable* increase in flight speed, which is much less distracting to the user, which aids them in maintaining a concentration on the lumen surface during the examination.

Medical Visualization as a Service

The problem with existing hardware/software solutions for 3D/4D medical visualization is that it is product-oriented. This means that the typical user of medical visualization must purchase and install software and/or hardware to perform tasks. This requires considerable investment and resources and training to maintain. With the ever-increasing connectivity provided by the World-Wide Web (WWW), there is no longer a necessity to deploy software as a product. Instead, the medical visualization can be offered as service to be used on demand and without considerable initial investment. By having the service run in a server-centric environment, the investment is shifted to the service provider.

In the proposed scenario, a user of medical visualization such as a radiologist will select a service provider and set up a secure account with the provider, thus establishing a secure link for the transferring of medical data. The user will then select a 3D or higher-dimensional dataset from their CT scanner or PACS archive and securely send the data to the service provider using the WWW. The service provider will perform a manual or automatic post-processing (such as segmenting organs, performing diagnostic procedures, or calculating features). The user will then be able to obtain the results in real-time over the secure network. The user will be able to interact with the server over the network to adjust the visualization or perform more post-processing as needed. When the user is satisfied with the results, the images can be automatically stored in the local PACS archive for long-term storage.

An alternative is for the service provider to automatically send back the results when completed to the user's PACS archive without user interaction.

An advantage of this invention is that the user is not required to purchase or maintain software and hardware in order to obtain the desired services. Also, upgrades to the processing algorithms on the server are transparent to the end user.

Automated organ extraction and post-processing

Background of the Invention

The present disclosure relates to the automatic processing and distribution of medical images.

Radiologists are able to examine the inner structure of the human body by examining 2D cross-sectional images generated by CT or MR. Recently, the thickness of these slices is shrinking exponentially (by a power of two every 12-18 months) and the number of slices necessary to cover the same anatomy growing exponentially. This leads to the situation in which the quality of the diagnostic information is increasing, but the means to digest the growing amount of information is rapidly decreasing. Thus, new techniques are necessary to efficiently manage the growing amount of information.

Three dimensional (3D) imaging is one means to rapidly assimilate many layers (or slices) of information simultaneously. This generally requires the use of specialized hardware, software, and technical personnel to specify and generate the images and to get them into the hands of the doctors for diagnosis. One of the most user-intensive steps is to separate the diagnostically useful 3D raw data from the not useful in a step that is usually referred to as segmentation. It requires a general knowledge of the desired anatomy and it usually requires several steps to identify and separate (or cull) the information using user-interactive techniques such as drawing, cutting, thresholding, filling, growing, and shrinking. These techniques are used either on a sequence of adjacent 2D slices or directly within a virtual 3D space on the computer screen. After the desired objects are separated from their background, a set of images are prepared that provide diagnostically useful information to the doctors. The images are usually prepared and stored in electronic form for review directly on a computer screen or sometimes printed directly to some physical medium such as film for use in a standard radiologist's light box. The images can be

- select 2D images from the original acquisition
- 2D multi-planar reformatted (MPR) images either in an axis orthogonal to the original image plane or in any axis,
- curved MPR images in which all the scanlines are parallel to an arbitrary line and cut through a 3D curve, or
- 3D images using any projection scheme such as perspective, orthogonal, maximum intensity projection (MIP), minimum intensity projection, integral (summation), to name a few.

Furthermore, fused or combined images from multiple modalities (CT, MRI, PET, ultrasound, etc.) using any of the image types mentioned above can be generated to add to the diagnostic value, once the anatomy has been matched between the separate acquisitions.

In addition to the type of images desired, the appropriate number, size, color, quality, angle, speed, direction, thickness, and field of view of the images must also be selected. This choice varies significantly from doctor to doctor, but it is usually related or proportional to the size, shape, and/or configuration of the desired object(s).

Because of all these reasons, 3D imaging is time consuming to generate because it requires knowledge of the anatomy for object selection and image generation. It is desirable to automate these processes to eliminate much of the costly time and tedium required to generate the final output.

Summary of the Invention

Many technologies are available that, when combined, can eliminate most or all of the user-interaction required to generate diagnostically useful images. There have already been techniques developed to automatically identify and segment the colon, lung, bones, heart, brain, and blood vessels from a scan of the human body. Nearly every part of the body can be automatically identified and segmented if sufficient distinguishing features are available. Sometimes a little bit of user interaction is required to direct the computer algorithms to focus on the correct part of the body. For instance, the user may be required to provide one or two clicks on the correct blood vessel since there can be tens to hundreds to choose from. Other algorithms may be more highly automatic and require no user interaction, such as the identification of the lungs, which are highly visible due to their distinct structure.

At a higher level of refinement are automatic algorithms that take a segmented body part, such as the lungs or the colon, and attempt to identify and diagnose abnormalities in the part. These algorithms are generally called computer aided diagnosis (CAD) algorithms and are becoming increasingly more acceptable as a factor in medical diagnosis. These algorithms may provide further information about the body part such as principal dimensions, central axis, likelihood of malignancy, growth rate, potential severity, and details of the structural composition. All of this information is desirable to have available alongside or imprinted directly onto the final images.

In order for a user to generate a set of images, they generally follow a prescribed protocol or set of instructions that generates a set of images with the most diagnostically useful information for the doctor. Because every person's anatomy is unique, the instructions are all relative to the individual anatomy. For example, it may be desired to generate a set of images through the carotid artery, a branching structure that makes visible the three primary vessels at the bifurcation all in a single plane. There is one unique plane that passes through the three vessels and an MPR image can be aligned to the plane to image the vessels most clearly. That MPR image plane can be slid back and forth parallel to itself to generate a set of images that together cover the entire vascular structure. Another doctor may desire a set of images that takes the same three vessels, renders them using 3D volume rendering from the front side of the patient and rotates the object throughout 360 degrees around a vertical axis producing 36 color images at a specified resolution, one image every ten degrees. Still another doctor may desire to have each of the three vessels rendered independently using 3D MIP projection every 20 degrees, thereby producing three separate sets of images (movies) each with 18 frames.

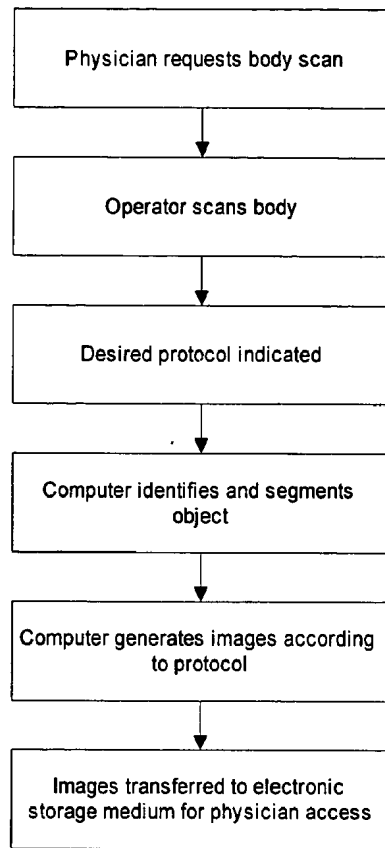


Figure 1: Process diagram of automated image generation

Once the structure of the anatomy is identified and segmented, it is entirely possible for the generation of images to be automated by a computer, once the desired protocol is indicated (see Figure 1). When a body scan is requested, the purpose of the scan is always indicated by the physician. The desired protocol needs to be identified to the automatic algorithms to begin the segmentation and image generation process.

Detailed Description

The automatic identification and segmentation of vascular structures is of particular importance because vascular studies represent a large proportion of the studies done in a real clinical setting, partly influenced by the current trend toward cardiovascular disease in the population. Vascular structures are a complex structure because they consist of multiple, branching tubular objects that all are numerous within the body and get increasingly smaller with each level of branching. Fortunately, image quality and resolution are increasing rapidly to the point where the majority of important vessels are highly visible if the scan is properly performed. For the computer to identify a particular vascular structure, it must have some knowledge of how the structure should appear within the raw data. In particular, a vascular structure should contain many of the following characteristics:

- Location within the body
- Direction relative to the body

- Length of section of vessel
- Curvature of the vessel centerline
- Axis of curvature
- Diameter
- Area
- Intensity of interior of vessel
- Texture features of interior of vessel (e.g., grainy, homogenous)
- Intensity of exterior of vessel
- Branch location and connectivity to other vessels

The structural characteristics of a vessel need to be defined parametrically along the length of the vessel which, in turn, defines the overall shape of the vessel. Furthermore, the characteristics of the vessel all need to be defined as not only a target value, but also with a desired range of values for each. For instance, the diameter needs to be defined not only as a target diameter as well as a minimum and maximum diameter. The minimum and maximum values can be interpreted as both hard limits (everything outside of the range is rejected) or as highly desirable such that a majority (fixed percentage) of the vessels will fall within the given range, similar to a standard deviation. Furthermore, the characteristics can apply over various ranges, small or large. For instance, the local direction of a vessel may vary significantly, but the overall, composite direction may be relatively invariant. Also, the relative weight of the characteristics may be varied in order to better select the correct vessel when faced with a choice among several options.

The vessels can be identified as follows. First, the probability of the presence of a vessel is determined at every voxel location in an input dataset of CT, MR, or other modality 3D image. The technique used here varies, but can be any technique that recognizes the shape and/or intensity profile characteristic of a vessel. Then, a higher-level recognition algorithm connects the voxels within the dataset that meet a certain threshold. One method to do this is by finding seed points (of the highest probability of being a vessel) either randomly or deterministically. These seed points can be grown in the most probable vessel direction using the vessel probability of the neighboring voxels. The seeds then grow into long sets of voxels that are probably the locations of vessels. These sets of connected regions are then analyzed to determine the most likely groups that represent a vascular structure. The structure will probably consist of multiple branching vessels and these branches must be noted and identified as characteristics. Then, each of the probable vessels is analyzed to extract as much of the characteristics over the length as possible. At any point after recognition, the vessel centerline can be extracted and optimized (e.g., using the techniques disclosed in provisional application serial number 60/525,603 which is incorporated herein by reference) for better visualization. The next phase is the matching of the probable vessels in the unknown dataset with the known anatomical vessels. This may be done by any matching method that matches multiple sets of features to multiple sets of features. One example method for matching is that described in U.S. application serial number 10/496,430, incorporated herein by reference. The general idea is to get the best-fit match between the two sets first, then to eliminate the two sets from consideration and repeat until all unknown vessels are determined. By finding the most probable match first, it helps to find the other vessels due to the

connections and placement of the other vessels in relation to the matched vessels. In general, the method to recognize and identify vascular and other structures in the body is a multi-level approach which recognizes small, local features as well as larger, aggregate features based on groups of smaller features. The number of levels as well as the direction of recognition (bottom-up or top-down) is not important.

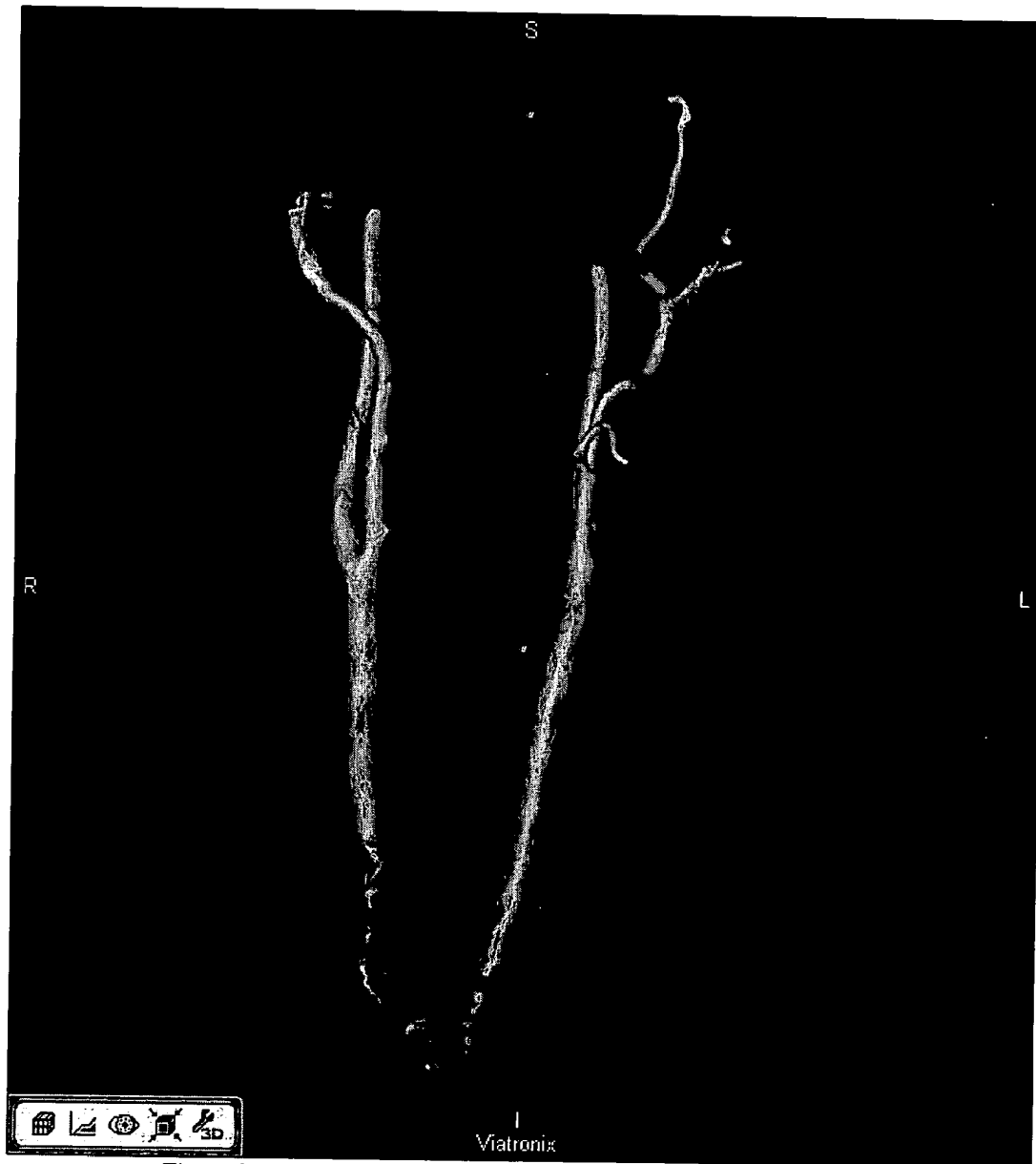


Figure 2: Example of automatically extracted internal carotid arteries

Note that the method can be extended to recognize other objects as well as vessels. For instance, it can be used to identify bones in the body such as vertebrae or other organs. To do so, the underlying mechanism for identifying prospective objects needs to be extended to locate non-tubular shapes. The advantage is that the more objects are recognized and placed within the body; the more can be inferred about the remaining

parts. Tubular shapes are just one example of a recognizable feature. They are identified at the lowest level by their characteristic signature – a cylindrical shape generally composed of a higher intensity cylinder embedded in a lower intensity surrounding (although the intensities could just as easily be reversed). A mathematical characterization, such as a Hessian filter, a Hough transform, or any other shape/structure/texture recognition or combination of these can be employed to characterize individual features, and then these features can be hierarchically determined using characteristic groups of features arranged in a characteristic way. These groups, in turn, can be categorized into features and again grouped to form even higher level features. The net effect is a hierarchical recognition of objects composed of multiple distinctive features.

After the vessels or other body parts are recognized by the automatic algorithms, they can be labeled for future manipulation and visualization. If desired, various automatic visualization techniques can be applied in order to aid in diagnosis. Often, these visualization techniques are applied interactively by a technician, as described above, but the computer can automatically generate the desired visualization to save time and effort.

The desired segmentation and visualization protocols can be automatically determined based on some information either within the image data (if it looks like a heart, then process it as using the heart protocol; if it looks like a lung, processes it using the lung protocol), meta-data attached to the image (e.g., using one of the ‘tag’ fields in DICOM), or by user-input configuration at the computer console.

In more detail, one possible mechanism by which to indicate the desired protocol is for the scanner operator to input the protocol to the scanner which encodes this information along with the image data after the scan is completed. Another mechanism is for a person to select on the computer the desired protocol from a list of available protocols. Another mechanism is for the computer to automatically determine the protocol using whatever information is available in the image data (if it looks like a heart, use the heart protocol, etc.) and the metadata that comes along with each image (e.g., the referring physician’s name is “Jones” and he prefers protocol “A” for heart scans, except for short, female patients with heart scans he prefers protocol “B”). As can be seen, the possibilities for automatic selection are virtually unlimited because the protocol can be derived from so many factors including the unique data scanned in every image.

For every type of anatomy, there is usually as set of visualization techniques that are optimal for diagnosis. For looking at vessels, it is desirable to visualize the vessel in a curved MPR view and a rotating 3D view. For lung nodules, a “cartwheel” projection that shows a small square oblique MPR view that rotates 180 degrees around a central axis of a suspected lung tumor. For virtual colonoscopy, it is desirable to have a 3D flythrough along the entire length of the colon. To obtain these images, a technician must spend time creating these views or the doctor must create these views himself. Once the views are created, a subset of the views is sent to a digital archive for short and/or long term storage. From there, the physician can view the original source images along with any of the derived images to make a diagnosis. The doctor will either locate suspicious

locations in the original images and confirm diagnosis using the derived images or vice versa. In any case, the generation of the protocol specific images can be automatically generated and saved in a convenient location using the automatic methods described herein.

The general practice in modern radiology departments is for all digital images to be stored in a Picture Archiving and Communication System (PACS). Such a system centralizes and administrates the storage and retrieval of digital images from all parts of the hospital to every authorized user in a hospital network. It usually is a combination of short-term and long-term storage mechanisms that aim to provide reliability, redundancy, and efficiency. To read images within such a system, the radiologists usually selects a patient and the “series” or sets of images in the study are recalled from the PACS and made available for examination on a PACS viewer usually on a standard personal computer.

The following is a description of the creation of customized movies of vessels. After carotid vessels are automatically found and segmented, a set of customized movies are created. These movies are defined in an XML script file that is customizable on a user-by-user basis. An animation script consists of a set of animations as shown below in the following sample.

```
<?xml version="1.0" encoding="utf-8"?>
<animations version="1.0">
  <animation name="Full Volume" version="1.0">
    <preset version="1.0" name="CTA, Carotid" number="0" />
    <componentVisibilities version="1.0" defaultVisible="true">
    </componentVisibilities>
    <animator version="1.0">
      <action version="1.0" typename="Viatronix.v3D.Animations.AnimationActionRotate3D,
Viatronix.v3D.Visualization">
        <AxisOfRotation>y</AxisOfRotation>
        <DegreesPerImage>10</DegreesPerImage>
      </action>
      <capture version="1.0" typename="Viatronix.v3D.Animations.AnimationCaptureMovie_vi,
Viatronix.v3D.Visualization">
        <ImageWidth>256</ImageWidth>
        <ImageHeight>256</ImageHeight>
        <FramesPerSecond>10</FramesPerSecond>
      </capture>
      <renderers>
        <renderer version="1.0" typename="Viatronix.v3D.Visualization.RendererCpu3D,
Viatronix.v3D.Visualization" />
        <renderer version="1.0" typename="Viatronix.v3D.Visualization.RendererOverlay3D,
Viatronix.v3D.Visualization" />
        <renderer version="1.0" typename="Viatronix.v3D.Visualization.RendererOverlay,
Viatronix.v3D.Visualization" />
      </renderers>
      <renderingQuality value="default"/>
      <font family="Arial" size="12"/>
    </animator>
  </animation>
  <animation name="All Vessels" version="1.0">
    <preset version="1.0" name="CTA, Carotid" number="2" />
    <componentVisibilities version="1.0" defaultVisible="true">
      <componentVisibility name="Background" visible="false" />
    </componentVisibilities>
    <animator version="1.0">
      <action version="1.0" typename="Viatronix.v3D.Animations.AnimationActionRotate3D,
Viatronix.v3D.Visualization">
        <AxisOfRotation>y</AxisOfRotation>
```

```

        <DegreesPerImage>20</DegreesPerImage>
    </action>
    <capture version="1.0" typename="Viatronix.v3D.Animations.AnimationCaptureMovie_vi,
Viatronix.v3D.Visualization">
        <ImageWidth>512</ImageWidth>
        <ImageHeight>512</ImageHeight>
        <FramesPerSecond>15</FramesPerSecond>
    </capture>
    <renderers>
        <renderer version="1.0" typename="Viatronix.v3D.Visualization.RendererCpu3D,
Viatronix.v3D.Visualization" />
        <renderer version="1.0" typename="Viatronix.v3D.Visualization.RendererOverlay3D,
Viatronix.v3D.Visualization" />
        <renderer version="1.0" typename="Viatronix.v3D.Visualization.RendererOverlay,
Viatronix.v3D.Visualization" />
    </renderers>
    <renderingQuality value="highest"/>
    <font family="Arial" size="12"/>
</animator>
</animation>
</animations>

```

In this sample, the first animation is a 256^2 image of the entire dataset in 3D rotating about the vertical (Y) axis with 36 frames at 10 frames per second. It chooses the first (index 0) preset that matches the “Carotid, CTA” name. It turns on all the components and renders with the default rendering quality. The second animation is eighteen 512^2 images rendered at the highest quality at 15 frames per second. It turns on all the components, and then specifically turns off the Background component, leaving just the automatically segmented vessels.

If we had specified `regex="Internal"` instead of `name="Background"` within the component visibility, it would have turned on all of the internal carotid arteries because the regular expression "Internal" matches both “Left Internal Artery” and “Right Internal Artery.” We could have also used `regex="Left"` in order to display all the left side arteries or `regex="Right"` for just the right side arteries. The use of `name=` implies that only an exact match should be considered while the use of `regex=` implies that any matching of the regular expression in a component includes it for consideration. In the case of a tie or conflicting rules, the order of specification should override the conflict.

The computer-generated images could also be a combination of multiple kinds of images and information, drawn together to provide a richer set of information in each single image. These images are combined and all updated synchronously to provide contextual or numerical information about the current diagnostic image. For instance, a vessel examination can benefit from having a combination of overview, vessel view, and detailed vessel view all combined into a single image as shown in Figure 3.

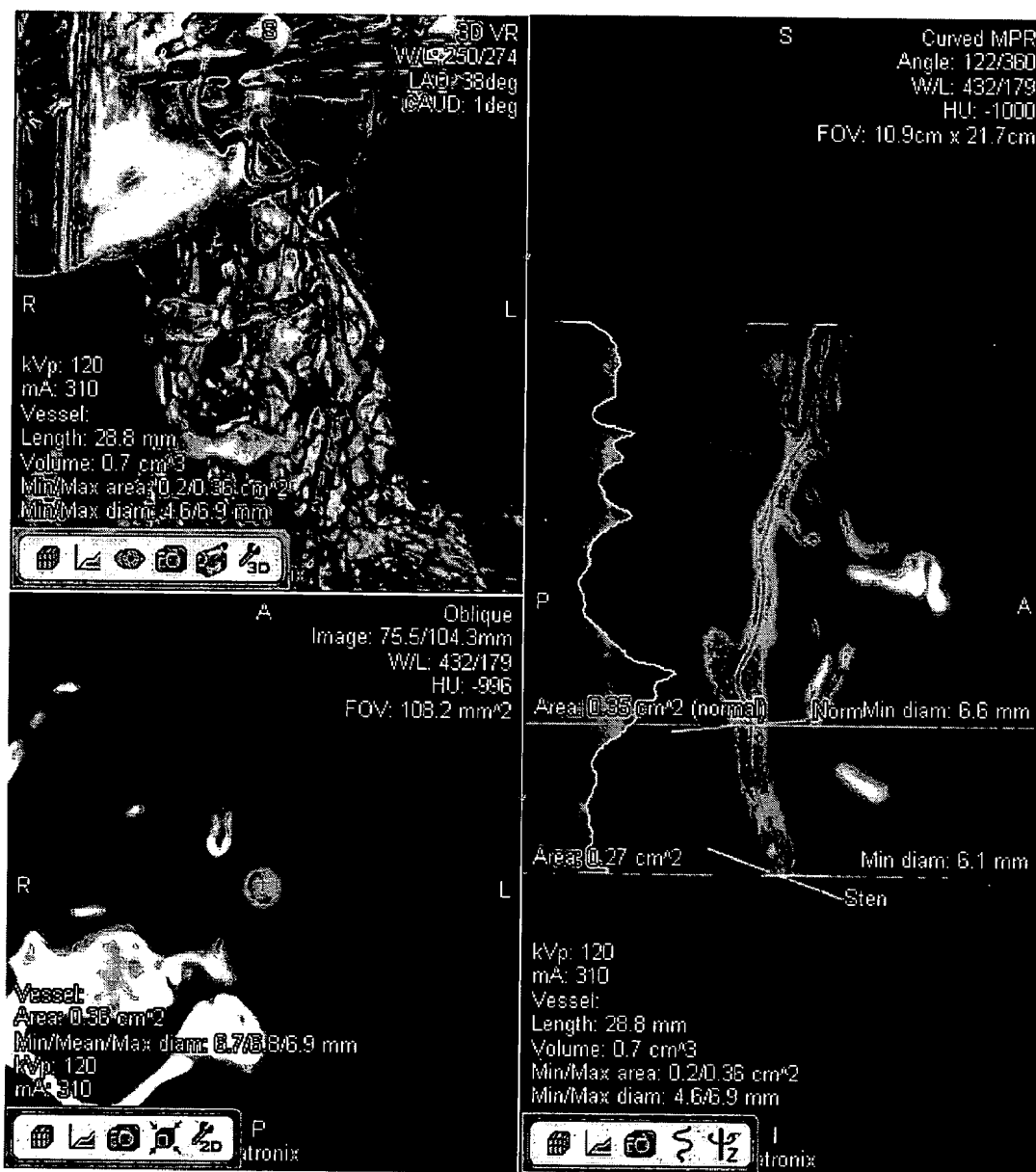


Figure 3: Specialized vessel view showing overview (upper left), vessel view (right), and detail view (lower left)

As another example, Figure 4 shows a frame from a virtual colonoscopy animation in which a virtual endoscope travels along the centerline of a colon. An overview image showing the entire colon (yellow shape), the colon centerline (green curve), points of potential interest (red circles), and the current camera position (blue arrow) is overlaid of inset into the main image to provide additional contextual information.



Figure 4: Specialized display for virtual colonoscopy showing large endoscopic image with inset overview image.

For lung studies, it is desirable to have an automatic algorithm process a data set to locate suspicious regions and evaluate them for malignancy or other characteristics. Then, various views of the suspect anatomy can be generated according to some user-specified protocol and images generated with supporting information possibly superimposed or attached as meta-data. Finally, the computer-generated results can be stored as digital images in a standard digital format (e.g., DICOM) in a standard digital archive (e.g., a PACS) so that during diagnosis of the original images, the associated computer-generated images can be reviewed within the conventional diagnostic environment.

For cardiac studies, it is desirable to visualize the heart chambers using so-called long and short axis views. To do so, the heart must first be recognized along with its major

axis. Then, double oblique MPR images cut through the heart in the planes of equal longitude and latitude – these are the short and long axis views. With sufficient contrast enhancement, the blood-filled chambers (ventricles) of the heart can be segmented from the rest and the various computations made comparing the volume of the ventricles at different times during the heart cycle. The result of these computations and possibly textual and visual information on the results can be formatted into one or more information-rich images. These images can then be sent to the PACS archive or to a web server or some other accessible digital storage devices that is normally used as a source from which to draw images for diagnosis.

Similar procedures exist for other specialized examinations such as brain, carotid, colon, aorta, trauma, spinal column, kidney, liver, knee, bladder, etc. The desired processing protocol and visualization protocol specifying the desired images can be provided and customized by the user.

Additional information can be supplied and attached to the images. The information can either be displayed directly within the images (such as the distance from the rectum in a virtual colonoscopy, or the length/diameter/volume of a vessel in vessel analysis) and/or it can be embedded or attached to the image as meta-data. For instance, in vessel analysis, a full 3D description of the shape can be converted to a standard (e.g., XML) format and embedded into the image. If the image format is DICOM format, then special DICOM fields and extensions of them (i.e., private fields) are available to store additional data. DICOM data can also hold additional binary-formatted data at the end of the image that is retained throughout transfer, is readable by any reader, but not visible to the typical user since it is beyond the visible bounds of the pixel data. If the image format is PNG, then additional data chunks are available within PNG to store any additional data.

The advantage of the present invention is the automatic generation of computer-processed results performed according to a customizable protocol with the results being easily accessible within the existing diagnostic environment.

Claims

What is claimed is:

1. An automatic method for accepting a set of at least one images of at least one object, the method comprising:
 - processing said at least one images to extract at least one known object;
 - accepting a set of at least one directives specifying the desired output;
 - generating at least one images in a standard digital imaging format according to the at least one directives; and
 - transferring at least one generated images to a digital archive.
2. A method as defined in Claim 1 wherein the digital archive is a hard disk.
3. A method as defined in Claim 1 wherein the digital archive is a standard medical archive system (e.g., a PACS archive).
4. A method as defined in Claim 1 wherein the object is an organ within a body.
5. A method as defined in Claim 4 wherein the organ is a blood vessel.

6. A method as defined in Claim 5 wherein the processing of at least one images extracts tubular objects by filtering the input data with a filter for tubular objects.
7. A method as defined in Claim 6 wherein the tubular objects are identified by matching with a set of known blood vessels for characteristics such as position, direction, curvature, diameter, connection to other objects, and relation to other objects.
8. A method as defined in Claim 1, wherein the at least one generated images include a 2D multi-planar reformatted image displaying cross-sectional cuts through the object.
9. A method as defined in Claim 1, wherein the at least one generated images include a 3D view of the at least one object.
10. A method as defined in Claim 1, wherein the at least one directives include the generation of a plurality of images that when played in sequence simulate a continuous transformation (e.g., rotation, translation, a combination of rotation and translation) of the object or viewpoint.
11. A method as defined in Claim 9, wherein the plurality of 3D images simulates the movement of an endoscope through a visually hollow organ within a body.
12. A method as defined in Claim 11, wherein the organ is at least one blood vessel.
13. A method as defined in Claim 11, wherein the organ is a colon.
14. A method as defined in Claim 11, wherein the organ is a heart.
15. A method as defined in Claim 11, wherein the organ is a lung or part of a lung.
16. A method as defined in Claim 1, wherein the generated images are combined together by juxtaposition or inset and the information synchronized if possible.
17. A method as defined in Claim 1, wherein computer-generated meta-information is combined with the image and either displayed within the image or attached to the image as supplemental information allowing readers of the image to retrieve the information and obtain diagnostic numerical information, computer-enhanced data about the object in the image, or shape information about the object in the image.

System and Method for Building the Library of Digital Tissue and its Application to Lesion Detection and Staging

Background

The repaid advance in medical imaging technology provides much better tissue contrast than before. The improved tissue contrast allows detecting the subtle difference between normal and abnormal, or benign and malignant tissues in the medical images. More important, the better quality images provide much stable characteristics for digitally comparison of virtual samples that are taken out from image series which are acquired at different time sections. This made the virtual histology (or digital histology) possible. It also opens great opportunities for lesion or tumor staging based on medical images. In the following, we describe the general scheme of virtual histology first. Then, we shall describe an application to virtual colonoscopy as an example.

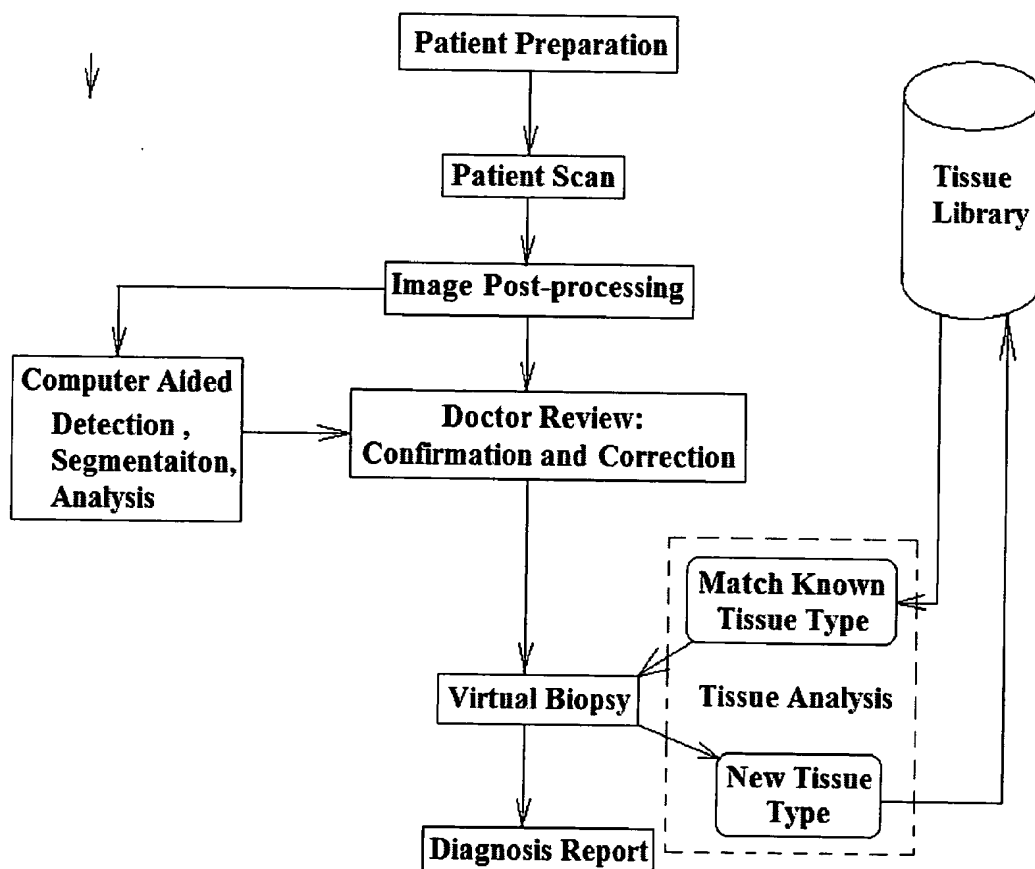


Figure 1. The flow chart demonstrates the work flow of virtual histology. The digital tissue library is a collection of typical digital samples and their intrinsic characteristics in digital world.

General Scheme

Figure 1 is a flow chart for the virtual histology technology.

Patient will follow necessary preparation procedure in order to enhance or highlight certain type of tissue or lesion in the images. For example, the IV contrast agent injection for vessel enhancement in the CT angiograph application. The preparation may be done at patient's home or at the scanning suite. For example, patient orally intakes barium for highlighting residues in the colon. In general, the patient preparation may be any kind and may or may not be necessary.

A series of medical images is acquired from a subject at scanning suite after patient preparation. The images can be any modality with high resolution and good tissue contrast. The subject can be human being or animal. The computer system receives the medical images and post-processes them. The computer system can be directly connected to the image acquisition equipment or via a network. The post-processing can be multiple purposes. For example, image enhancement, noise deduction, organ segmentation, initial detection of abnormalities, building of 3D model for display, and etc.

After post-processing, the images will be loaded and display in medical imaging workstation in various display modes for physician review. The initial detected results by computer algorithm at post-processing step will be labeled and provided to physician for diagnosis assistance. After physician confirming an abnormality, he/she can use the mouse click on the target. Then, the system will automatically/interactively extract out the target sub-volume encapsulate that abnormality region. The sub-volume is the so-called Digital Sample for the abnormality. The sub-volume is not a merely group of voxels. It is extracted based on the minimum size for representing a certain lesion or abnormality tissue functions. It should provide the basic functional clue for pathology analysis.

A database of digital samples will be built. The initial digital samples in the database will be used for feature selection. The unique features related to a specific type of abnormality will be extracted for all digital samples of that type. The features must be essential characteristics for the specific type of abnormality. In other words, an indicator of tissue type for that kind of abnormality can be constructed based on those features and the indicator must have high sensitivity for characterization of the specific abnormality.

Note, the features and the built indicator for a specific tissue type are associated to the digital sample, as a whole tissue sample with certain bio-function rather than a group of voxels. This is completely different from that of conventional CAD (computer aided detection) approaches. In conventional CAD approach, the extracted feature is related to independent voxel or a group of voxel, where the entire digital sample had never been considered at its feature extraction stage. In other words, the conventional CAD approach works on collection of fragment information of a tissue type and try to put them together to get a conclusion. Instead, the virtual histology works on the complete tissue sample as whole at the very begin. The features that are extracted from digital sample must be global rather than voxel-wise to the tissue type or type of lesion.

For certain lesion type, the initial features and the tissue indicator will be collected and developed in a digital sample library. More precisely, the digital sample library is a categorized database for features and digital sample indicators. When new digital sample is gotten, the features that extracted from the new sample will compare to those in the library. Using the tissue indicator of the library, one can get a conclusion that the new digital sample is most probably a certain type of known tissue in the library.

Data-mining technology should be employed for improving and enriching the library when more and more digital sample are available. The digital sample can stratified in different categories based on type of lesion or different stage of the same type of lesion. For example, benign and malignant polyps.

The most important point here is the consistency of the digital sample in physics characteristics. In other words, we assume that the medical images quality guarantee the same tissue type will have similar properties regardless of subjects and acquisition day. This is the basic assumption for the feasibility of virtual histology. Besides the image quality, the method of extracting digital sample is essential. It must segment out the correct sub-volume in a consistent way regarding the size, contour, voxel resolution, and the normalized voxel intensity.

Virtual Colonoscopy as an Example

The image acquisition procedure of virtual colonoscopy can be the routine one. The post-processing and display modes for physician review can be any of available. The only thing that triggers the virtual histology is a mouse click. By clicking on the suspicious polyp region, the virtual polypectomy algorithm is applied. The selected sub-volume of the target polyp will be delineated as the digital sample.

The initial suspicious polyp location can be either provided by CAD algorithm or by radiologist manual input.

In order to facilitate better understand, we use the shape feature as example to develop a polyp indicator. That should not limit our invention using only shape features for polyp indicator.

Polyp is growing inward to the lumen. Its shape is different from those of haustral fold and normal colon wall surface. It roughly has a convex cap like top with/without a stake. By developing a local intrinsic landmark system on the polyp sub-volume, a shape template can be developed, which should be invariant to translation and rotation (ref. Patent application by D. Chen et al. (2003): *Computer-Assisted Detection of Lesion in Volumetric Medical Image*), which is incorporated herein by reference. The shape templates that are collected from a training set can be classified to represent polyp (of different types), haustral fold, and normal colonic surface. A library of shape templates will be developed based on available digital sample of polyp. When new case comes in, the newly collected digital sample will be compared with the templates in the library for tissue confirmation. Figure 2 shows a polyp in endoluminal view. Figure 3 shows the extracted digital polyp sample that is coded in different color in the endoluminal view.

The maximum and minimum diameter and its volume are displayed. Figure 4 shows a digital sample of the dissected polyp that is stored in the library.



Figure 2. The polyp in the endoluminal view.

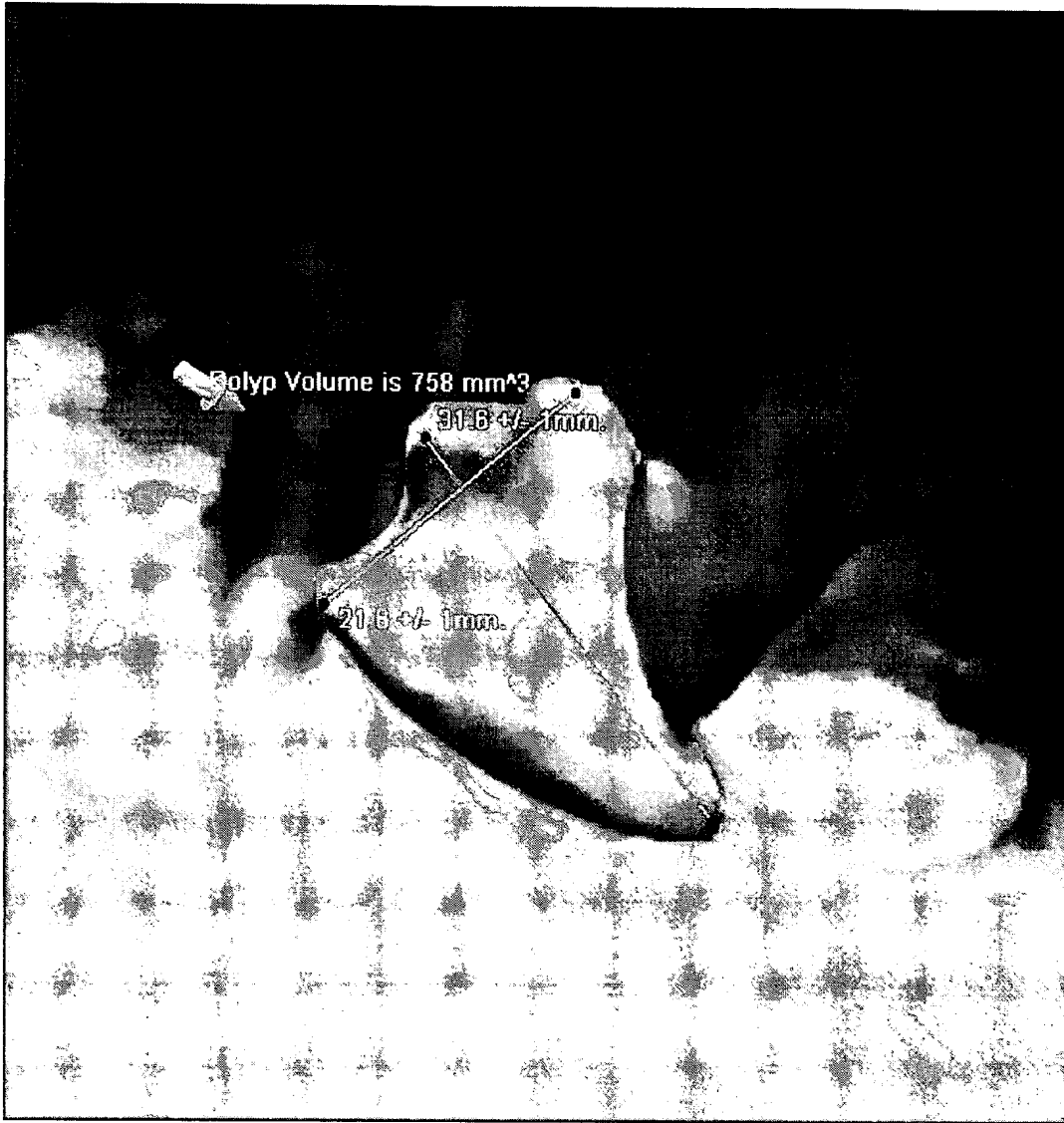
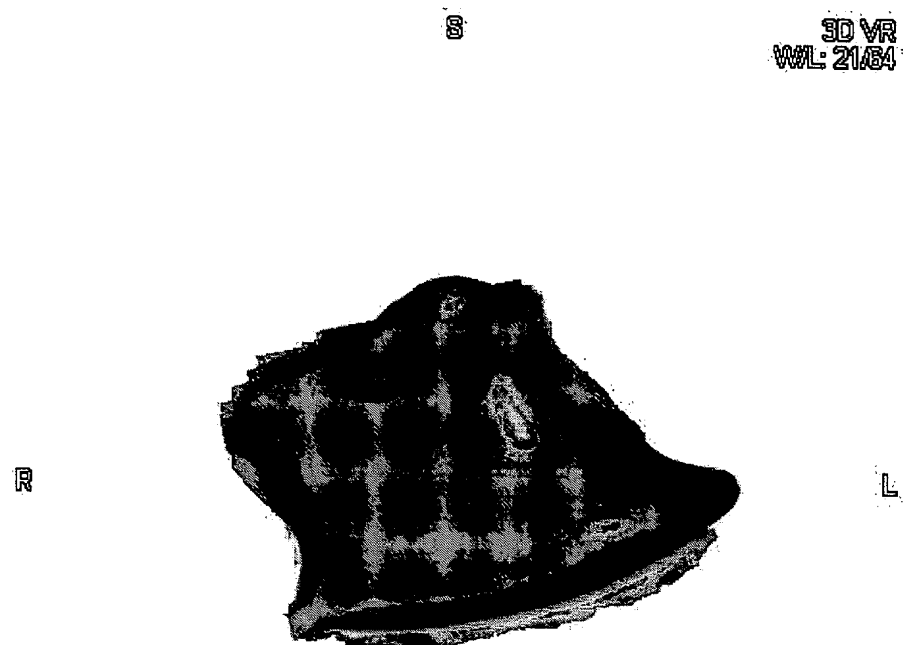


Figure 3. The polyp digital sample is coded in different color in the endoluminal. The maximum and minimum diameters and volume of the polyp are displayed.



Viatronix

Figure 4. The dissected polyp digital sample is showed in 3D view.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☒ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.